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IN THE

Supreme Court of the United States

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S,

Petitioners,

v.

CARACO PHARMACEUTICAL LABOR TORIES, LTD.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF IVAX PHARMACEUTICALS, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

HENRY DINGER, P.C.
Counsel of Record
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
(617) 570-1276

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QUESTIONS PRESENTED

(I) Whether the Federal Circuit erred, and deepened confusion among the lower courts, by holding that a declaratory-judgment plaintiff can establish traceability for purposes of Article III standing simply by alleging "but-for" causation between some action or conduct by the defendant and the plaintiff's asserted injury.

(II) Whether the Federal Circuit erred by holding that a declaratory-judgment plaintiff has standing where the plaintiff's complaint does not challenge the legality of the particular action or conduct alleged to have caused the plaintiff's asserted injury.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Ivax Pharmaceuticals, Inc. hereby states that it is a direct, wholly-owned subsidiary of Ivax Corporation, which is, in turn, wholly owned through the following chain: Teva Pharmaceuticals USA, Inc., Orvet UK Unlimited, Teva Pharmaceuticals Europe B.V., then Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded parent company of Ivax Pharmaceuticals, Inc. and no publicly-traded company owns more than 10 percent of its stock.

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STATEMENT OF INTEREST[1]

Ivax Pharmaceuticals, Inc. ("Ivax") holds tentatively approved Abbreviated New Drug Application ("ANDA") No. 76-765 for generic escitalopram oxalate tablets ("EO") in 5-, 10-, and 20-mg dosages. Because Ivax was the first generic EO applicant to challenge petitioner Forest's U.S. Patent No. 6,916,941 ("the '941 patent"), Ivax is entitled to a 180-day period of marketing exclusivity for generic EO under 21 U.S.C. § 355(j)(5)(B)(iv).[2]

As the court below recognized, respondent Caraco's declaratory judgment action — which requests a judgment that its EO products do not infringe the '941 patent, even though petitioner Forest has covenanted never to assert the '941 patent against Caraco — seeks to trigger Ivax's marketing exclusivity before Ivax ever has an

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[1] All parties have consented to the filing of this brief, and letters evincing such consent have been filed with the Clerk. Pursuant to this Court's Rule 37.6, *amicus* states that no attorney for a party authored any part of this brief and that neither such attorney, nor any party, nor any person or entity other than *amicus*, its members, or its attorneys made a monetary contribution intended to fund the preparation or submission of this brief.

[2] This statute was enacted as part of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003). This legislation is commonly referred to as the "Hatch-Waxman Act," as Ivax will refer to it in this brief.

opportunity to take advantage of that statutory reward. Pet. App. 28a ("A favorable judgment in this case would clear the path to FDA approval that Forest's actions would otherwise deny Caraco — namely, using the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000) to activate Ivax's exclusivity period."). Ivax has a clear interest in preserving its legal entitlement to marketing exclusivity, and, thus, in the outcome of this case.

This case also presents recurring issues that are likely to have a significant long-term impact on Ivax's business, the generic pharmaceutical industry as a whole, and the federal courts. When Congress amended the Hatch-Waxman Act to create what it called a "civil action to obtain patent certainty," 21 U.S.C. § 355(j)(5)(C), this case decidedly was not what it had in mind. As the terminology employed by Congress suggests, that provision was intended to reduce delays in the resolution of *genuine* patent disputes between pharmaceutical manufacturers because Congress recognized that patent *un*certainty itself often deters the launch of generic drugs — even of generic drugs that have received FDA approval. *See Teva Pharms. USA, Inc. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342-44 (Fed. Cir. 2007).

Caraco, however, faces no patent uncertainty in this case, because Forest's covenant not to assert the '941 patent means both that Caraco's FDA approval is not blocked by that patent *and* that Caraco faces no conceivable patent liability for launching its EO products. As a result, the decision below threatens to burden the courts with contrived patent infringement cases and, thus, to delay the resolution

of genuine patent disputes like the many in which Ivax currently is involved.

But the decision below will do far more than permit litigants to clog the federal courts with unnecessary claims. It will fundamentally undermine one of the Act's most important features: 180 days of marketing exclusivity for the first generic applicant to challenge a pharmaceutical patent that otherwise would block the introduction of generic competition. When Congress enacted the statute, it deliberately chose to reward that first generic applicant with a period of marketing exclusivity in order to encourage generic companies to undertake the significant expense associated with developing a generic product and to assume the risks associated with high-stakes patent litigation. *See, e.g., Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361 (Fed. Cir. 2008) ("The 180-day exclusivity period is important to generic pharmaceutical companies as it promotes patent challenges by enabling a generic company a period to recover its investment in these challenges."). The appellate court's decision in this case, however, encourages subsequent generic applicants to knock out the first-filer's exclusivity by challenging a patent that the brand manufacturer has (validly and enforceably) pledged never to assert against the subsequent generic applicant.

This Court thus should have no illusions about the consequences of the panel's decision. If generic companies can bring declaratory judgment actions directed at patents that cannot be enforced against them, and by so doing eliminate a competitor's marketing exclusivity, they will do so at every

opportunity. That not only will undercut the statutory incentive scheme by rendering the 180-day exclusivity period vulnerable to manipulative patent litigation by third parties — reducing the incentive for generic manufacturers to file paragraph IV certifications in the first place, and thereby slowing the onset of generic competition over the long run — but also will flood the courts with burdensome patent cases where nothing is at stake because the patents-in-suit never will (and never can) be asserted against the plaintiff that challenges them. Beyond its specific interest in this case, then, Ivax has a strong interest in protecting the exclusivity incentive against unproductive, self-serving, and shortsighted challenges like Caraco's.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The Federal Circuit's decision in this case stretches the boundaries of Article III beyond the breaking point, and opens the door to contrived litigation over questions not genuinely in dispute. In the process, the Federal Circuit contributed to the lower courts' deep and abiding confusion over this Court's standing jurisprudence, and took aim at one of the most important features of the Hatch-Waxman Act — the 180-day period of marketing exclusivity awarded to the first generic drug applicant that challenges a brand-manufacturer's pharmaceutical patents.

If left intact, the appellate court's overly expansive view of Article III jurisdiction would undermine a statutory incentive that many believe to be responsible for *hundreds of billions of dollars* in healthcare savings over the past two decades, with

dire consequences for the *millions of patients* who depend on safe and affordable generic medications to treat their illnesses. While the broad jurisdictional implications of the Federal Circuit's decision would warrant this Court's review in their own right, the fact that they arise in this particular context makes review in this case imperative.

The issues raised by the Federal Circuit's decision cut to the heart of the Constitution's standing requirements. First, the appellate court erred, and in the process deepened confusion among the lower courts, by holding that mere but-for causation between a defendant's actions and the plaintiff's asserted injuries invariably suffices to establish the "traceability" requirement of Article III standing. In particular, the Federal Circuit held in this case that Caraco's asserted injury — namely, that Ivax's statutory right to marketing exclusivity temporarily bars FDA from approving Caraco's ANDA — was sufficiently "traceable to Forest" because Forest's decision to list the '941 patent in FDA's official list of drug-claiming patents (the "Orange Book") gave Ivax the chance to garner the allegedly injurious exclusivity period by filing the first patent-challenging "Paragraph IV" certification to the '941 patent. Pet. App. 26a (capitalization omitted).

The problem with that analysis is that Ivax's intervening actions fundamentally sever the chain of causation between Forest's initial patent-listing decision and Caraco's asserted injury. After all, as the Federal Circuit itself recognized, Caraco is "injured" by Ivax's statutory exclusivity period *only* because Ivax, which is not a party to this case, filed the first Paragraph IV certification to the '941 patent

(Caraco was *seventh*). Pet. App. 16a, 19a-20a. Had *Caraco* filed the first Paragraph IV certification to the '941 patent instead of sitting on its rights, Forest's patent-listing decision would not have injured Caraco at all; instead, Caraco would have earned the very exclusivity period about which it complains.

The appellate court, however, held that that clear break in the causal chain between Forest's allegedly-injurious conduct and Caraco's asserted injury was constitutionally irrelevant simply because Forest's initial decision to list the '941 patent was a "but-for cause" of Caraco's asserted injury. Pet. App. 26a ("Such but-for causation is sufficient to satisfy the traceability requirement of Article III standing.") (citing *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n.26 (1978)).

That was error. Indeed, this Court long has held that — even where a defendant's actions contribute to a plaintiff's injury — the plaintiff lacks standing where the asserted "injury ... results from the independent action of some third party not before the court." *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976); *Warth v. Seldin*, 422 U.S. 490, 504-05 (1975). That, of course, perfectly describes what happened in this case: Caraco's injury results only from Ivax's independent filing of the first Paragraph IV certification to the '941 patent (and then only because Forest also covenanted not to sue Caraco for infringing the '941 patent).

Even so, the Federal Circuit's confusion is in some respects understandable. Notwithstanding this Court's decisions in *Simon* and *Warth*, several appellate courts have (just like the Federal Circuit in

this case) misread subsequent decisions by this Court to hold that mere but-for causation is all that standing's "traceability" requirement demands. *See, e.g., The Pitt News v. Fisher*, 215 F.3d 354, 361 (3d Cir. 2000); *Fulani v. League of Women Voters Educ. Fund [Fulani I]*, 882 F.2d 621, 628 (2d Cir. 1989).

The result is a three-way circuit split, with some courts holding that but-for causation is all that's necessary to establish traceability (*e.g.*, the Second Circuit in *Fulani I*, the Third Circuit in *Pitt News*, and the Federal Circuit in this case); some holding that mere but-for causation is not alone sufficient to establish traceability (*e.g.*, the D.C. Circuit in *Fulani v. Brady [Fulani II]*, 935 F.2d 1324, 1329 (D.C. Cir. 1991) and *Shoreham-Wading River Cent. School Dist. v. U.S. Nuclear Regulatory Comm'n*, 931 F.2d 102, 105 (D.C. Cir. 1991)); and still others holding that "something" between but-for causation and proximate cause is required (*e.g.*, the Tenth Circuit in *Nova Health Sys. v. Gandy*, 416 F.3d 1149, 1156 (10th Cir. 2005), and the Eleventh Circuit in *Focus on the Family v. Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1273 (11th Cir. 2003)).

This case thus offers an excellent opportunity to resolve the lower courts' deep and abiding confusion over the proper test for establishing traceability under Article III by affirming the bedrock principle that traceability cannot be shown where the plaintiff's "injury ... results from the independent action of some third party not before the court," whether or not some prior action by the defendant is a but-for cause of that injury. *Simon*, 426 U.S. at 41-42.

Even if the lower courts were not hopelessly confused over whether but-for causation is sufficient to establish traceability, review still would be warranted here because the Federal Circuit further erred by holding that a declaratory-judgment plaintiff has standing even though the plaintiff's complaint does not actually challenge the legality of the particular action or conduct alleged to have caused the plaintiff's asserted injury. As set forth above, the Federal Circuit held that Caraco had standing to pursue this action against Forest solely because Forest's decision to list the '941 patent in FDA's Orange Book eventually contributed to Caraco's asserted injury — namely, the fact that Ivax's statutory exclusivity (which is based on the '941 patent) temporarily will keep Caraco off the market.

The key point here, however, is that Caraco's complaint does not remotely allege (much less seek a judgment) that Forest's decision to list the '941 patent in FDA's Orange Book was itself unlawful, illegitimate, or otherwise improper. Instead, Caraco's complaint merely seeks a declaratory judgment that its proposed generic EO products *would not infringe* the '941 patent. That question is fundamentally distinct from the issue of whether Forest properly listed the '941 patent in the Orange Book; indeed, the question of whether a generic applicant's drug products would infringe a listed patent has no bearing at all on whether the brand-name manufacturer properly listed that patent in the first place.

As a result, the Federal Circuit's decision squarely conflicts with a long line of cases holding

that the plaintiff's asserted injury must be based on "the defendant's *allegedly unlawful conduct*" in order to ground standing under Article III. *Allen v. Wright*, 468 U.S. 737, 751 (1984) (emphasis added); *see also Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

That requirement is no mere technicality: it is the essential prerequisite to an Article III case or controversy. After all, the Framers did not establish a federal Judiciary to remediate concededly lawful injuries; they established the federal courts to redress alleged legal wrongs. The Federal Circuit's contrary approach effectively writes the case-or-controversy requirement out of the Constitution, and effectively will require already-overburdened district courts to busy themselves rendering the very sort of advisory opinions that this Court has long foresworn.

The petition should be granted, and the Federal Circuit's decision reversed.

REASONS FOR GRANTING THE WRIT

I. The Federal Circuit Erred, And Deepened Confusion Among The Lower Courts, By Holding That A Declaratory-Judgment Plaintiff Can Establish Traceability For Purposes Of Article III Standing Simply By Alleging "But-For" Causation Between Some Action Or Conduct By The Defendant And The Plaintiff's Asserted Injury.

The Federal Circuit erred, and deepened confusion among the lower courts, by holding that a

declaratory-judgment plaintiff can establish traceability for purposes of Article III standing simply by alleging "but-for" causation between some action or conduct by the defendant and the plaintiff's asserted injury. Indeed, this Court held nearly thirty years ago that Article III standing "requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, *and not injury that results from the independent action of some third party not before the court.*" *Simon*, 426 U.S. at 41-42 (emphasis added); *see also Lujan*, 504 U.S. at 560-61 ("[T]here must be a causal connection between the injury and the conduct complained of — the injury has to be 'fairly traceable to the challenged action of the defendant, *and not the result of the independent action of some third party not before the court.*'") (quoting *Simon*; alterations omitted; emphasis added).

That perfectly describes what happened in this case. Caraco's asserted injury — its inability to secure immediate FDA approval as a result of Ivax's statutory exclusivity period — can be traced back to Forest's initial patent-listing decision *only* because third-party Ivax challenged Forest's listed patents before any other applicant and thereby earned 180-day exclusivity under the Hatch-Waxman Act. Accordingly, Caraco's injury unquestionably "results from the independent actions of some third party not before the court," and Caraco thus lacks standing to pursue its declaratory claims against Forest. *Simon*, 426 U.S. at 41-42; *Ne. Fla. Chapter of Ass'd Gen. Contractors of Am.*, 508 U.S. 656, 663 (1993) ("[A] party seeking to invoke a federal court's jurisdiction must demonstrate ... a causal relationship between the injury and the challenged conduct, by which we

mean that the injury fairly can be traced to the challenged action of the defendant, *and has not resulted from the independent action of some third party not before the court.*") (internal quotation omitted) (emphasis added).

The Federal Circuit nonetheless held that Caraco's injury was sufficiently traceable to Forest simply because Forest's initial decision to list the '941 patent was a "but-for cause" of Caraco's asserted injury, and "[s]uch but-for causation is sufficient to satisfy the traceability requirement of Article III standing." Pet. App. 26a (citing *Duke Power*, 438 U.S. at 74-78, 81 n.26). That holding lays bare the deep and abiding confusion among the lower courts over this Court's standing jurisprudence, and, in particular, over the strength of the causal connection that must be shown between a defendant's actions and the plaintiff's asserted injury in order to demonstrate traceability for purposes of Article III standing. The Federal Circuit's simplistic holding on this point — that "but-for" causation is all that Article III's "traceability" requirement demands — is not faithful to this Court's precedents, and directly conflicts with the decisions of other circuit courts.

Indeed, the Federal Circuit's holding on this point exacerbates a three-way split between the lower courts on precisely this point. The Second and Third Circuits have held — like the Federal Circuit here — that but-for causation alone suffices to establishes traceability for purposes of Article III's standing requirement. *See The Pitt News*, 215 F.3d at 360-61 ("We ... conclude that the injury alleged ... is fairly traceable to the enforcement of [the challenged law]. To analogize this situation to a familiar example in

tort law, the enforcement of [the challenged statute] was the cause-in-fact of the financial impact felt by [plaintiff]. 'But for' this enforcement, its advertisers would not have canceled their contracts."); *Fulani I*, 882 F.2d at 628 ("*But for* the government's refusal to revoke the [private defendant's] tax-exempt status, then, [the private defendant], as a practical matter, would have been unable to sponsor the allegedly partisan debates which caused the injury of which [plaintiff] complains. [W]e conclude that there is a nexus between the federal defendants' tax treatment of the [private defendant] and [plaintiff]'s asserted injuries which enables [plaintiff] to trace her injury directly back to such federal defendants' tax treatment of the [private defendant]."") (emphasis in original).

On the other hand, the D.C. Circuit squarely has rejected the proposition (and *expressly* disagreed with its sister circuits) that but-for causation alone is sufficient to demonstrate traceability where there are "intervening causal factors." *See, e.g.*, *Fulani II*, 935 F.2d at 1329 ("[In *Fulani I*] the Second Circuit granted [plaintiff] standing to challenge the [private defendant]'s tax-exempt status because '*but for* the government's refusal to revoke the League's tax-exempt status, the [private defendant] would have been unable to sponsor the allegedly partisan debates which caused the injury of which [plaintiff] complains' .... By taking [federal action] as a given, however, the Second Circuit ignores the fact that the alleged traceability and redressability may be found in [*Fulani I*] — and could be found in the present case — only in combination with significant intervening causal factors.") (quoting *Fulani I*); *see also Shoreham-Wading River Cent. Sch. Dist.*, 931

F.2d at 105 ("While the ban on refueling may be a 'but for' cause of any such future rulings and thus of any resulting risks, the exemptions themselves will be the operative causes. The link with the refueling ban is simply too remote."); *cf. Huddy v. F.C.C.*, 236 F.3d 720, 724 (D.C. Cir. 2001) ("We question whether 'but for' causation of this sort could ever be sufficient to confer constitutional standing.... It seems improbable that the Court intends all its learning on constitutional standing to be so readily evaded.").

Finally, the Tenth and Eleventh Circuits have essentially thrown up their hands and declared that "something" between but-for causation and proximate cause is required to show traceability. *See, e.g., Nova Health Sys.*, 416 F.3d at 1156 ("As other courts have noted, Article III's causation requirement demands something less than the concept of proximate cause. Yet Article III does at least require proof of a substantial likelihood that the defendant's conduct caused plaintiff's injury in fact.") (citing *Focus on the Family*, 344 F.3d at 1273; quotation omitted)).

In fairness to the lower courts, however, much of their confusion on this point stems from tension within this Court's own precedents on traceability — and, in particular, on this Court's decision in *Duke Power*. In that case, plaintiff environmental groups and residents of an area surrounding a proposed nuclear power plant brought suit against the Nuclear Regulatory Commission ("NRC") and the operator of a proposed nuclear power plant, seeking a declaratory judgment that the Price Anderson Act ("PAA") unconstitutionally limited the liability of nuclear operators and effectuated a "taking" of the

plaintiffs' property in violation of the Fifth Amendment. 438 U.S. at 69. To support those claims, plaintiffs alleged (among other things) that the proposed plant could not be constructed in the absence of the PAA's liability cap, and that the plant's operation invariably would emit low-level radiation that would harm the local environment and reduce surrounding property values. *Id.* at 73.

The *Duke Power* Court began its standing analysis by holding that plaintiffs' asserted injuries were legally cognizable. *Id.* at 73-74. But when the Court turned to the next prong of the standing analysis — traceability — it immediately conflated that requirement with redressability. "The more difficult step in the standing inquiry is establishing that these injuries 'fairly *can be traced* to the challenged action of the defendant,' or put otherwise, that the exercise of the Court's remedial powers *would redress* the claimed injuries." *Id.* at 74 (quoting *Simon*, 426 U.S. at 41) (emphasis added). It then agreed with the district court's factual findings and legal conclusion that *the latter test* — redressability — was satisfied because "Duke would not be able to complete the construction and maintain the operation of the [proposed plants] but for the protection provided by the [PAA]." *Id.* at 74-75 (quoting district court opinion); *id.* at 75 & n.20 ("These findings ... if accepted ... would likely satisfy the second prong of the constitutional test for standing as elaborated in *Simon*. Our recent cases have required no more than a showing that there is a 'substantial likelihood' that the relief requested *will redress the injury claimed to satisfy the second prong of the constitutional standing requirement.*") (citing *inter alia Simon*, 426 U.S. at 38; emphasis added).

Since *Duke Power*, of course, this Court has made clear that traceability and redressability are distinct requirements. *Steel Co.*, 523 U.S. at 106 n.7 ("[The dissent] also seems to suggest that redressability always exists when the defendant has directly injured the plaintiff. If that were so, the redressability requirement would be entirely superfluous, since the causation requirement asks whether the injury is 'fairly ... traceable to the challenged action of the defendant, and not ... the result of the independent action of some third party not before the court.'") (alterations omitted); *Allen*, 468 U.S. at 753 n.19 ("The 'fairly traceable' and 'redressability' components of the constitutional standing inquiry were initially articulated by this Court as 'two facets of a single causation requirement.' C. Wright, *Law of Federal Courts* § 13, p. 68, n. 43 (4th ed. 1983). [But] the former examines the causal connection between the assertedly unlawful conduct and the alleged injury, whereas the latter examines the causal connection between the alleged injury and the judicial relief requested. Cases such as this, in which the relief requested goes well beyond the violation of law alleged, illustrate why it is important to keep the inquiries separate.").

Yet *Duke Power*'s unclear approach continues to produce confusion among the lower courts, with some (including the court in this case) improperly applying *Duke Power*'s "but-for" redressability analysis in the course of assessing traceability and then ignoring the significance of intervening breaks in the causal chain. Indeed, this case perfectly illustrates the point. No one disputes that Caraco's injury would be redressed if it obtained a judgment that its proposed

EO products would not infringe Forest's '941 patent. After all, such a judgment would trigger Ivax's statutory exclusivity period, and once that 180-day period expires, Caraco would be free to enter the market. Pet. App. 27a-28a.

But the fact that litigation success will redress Caraco's asserted injury does not suffice to demonstrate the existence of a sufficiently traceable link between the plaintiff's injury and defendant's conduct. Instead, to reiterate, Caraco's asserted injury in this case was not caused in any meaningful sense by Forest's patent-listing decision; it was instead caused by the fact that Ivax beat Caraco to the punch, and thereby earned the allegedly injurious marketing exclusivity period by filing the first Paragraph IV certification to the '941 patent. Under these circumstances, Ivax's intervening actions fundamentally sever the link between Forest's patent-listing decision and Caraco's injury. Regardless of whether this suit might redress those injuries, Caraco cannot pin the blame for its predicament on Forest and thus lacks Article III standing to pursue its declaratory claims against Forest.

This case therefore presents an ideal opportunity to clarify this Court's traceability jurisprudence and to correct the Federal Circuit's erroneous and overly simplistic holding that "but for" causation is the beginning and the end of that inquiry. Intervention is critical in this area to remedy the lower courts' deep and abiding confusion and preserve Article III's core limits on the exercise of federal jurisdiction.

II. The Federal Circuit Erred By Holding That A Declaratory-Judgment Plaintiff Has Standing Where The Plaintiff's Complaint Does Not Challenge The Legality Of The Particular Action Or Conduct Alleged To Have Caused The Plaintiff's Asserted Injury.

Even if naked but-for causation were sufficient to demonstrate traceability, the Federal Circuit further erred by holding that a declaratory-judgment plaintiff has standing where the plaintiff's complaint does not challenge the legality of the particular action or conduct alleged to be responsible for the plaintiff's asserted injury. Indeed, this Court repeatedly has held that Article III standing requires the plaintiff's suit to present precisely such a challenge. *See, e.g., Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000) ("[T]o satisfy Article III's standing requirements, a plaintiff must show [that its] injury is fairly traceable to *the challenged action of the defendant*.") (emphasis added) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998) ("[T]here must be causation—a fairly traceable connection between the plaintiff's injury and *the complained-of conduct of the defendant*.") (emphasis added); *Allen v. Wright*, 468 U.S. 737, 751 (1984) ("A plaintiff must allege personal injury fairly traceable to *the defendant's allegedly unlawful conduct . . .*.") (emphasis added); *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99 (1979) (plaintiff must "show that he personally has suffered some actual or threatened injury as a result of *the putatively illegal conduct of the defendant*") (emphasis added).

The requirement that standing requires the plaintiff to trace its injury to conduct actually challenged in the litigation makes perfect sense. If the Constitution permitted would-be plaintiffs to obtain a legal ruling by suing a defendant whose conduct has allegedly made them worse off — regardless of whether that conduct is the subject of the ruling sought or even alleged to be *unlawful* — then the federal courts effectively would possess general jurisdiction to issue advisory opinions that do not address concrete legal disputes between the plaintiff and defendant, and that are not even predicated on allegations of legal wrong.

That, however, is precisely what the Federal Circuit has permitted in this case. In holding that Caraco has standing to pursue a declaratory judgment that its proposed generic EO products would not infringe the '941 patent, the Federal Circuit reasoned that "Forest's listing of the '941 patent (the patent-in-suit) in the Orange-Book creates an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete." Pet. App. 27a; *see also id.* 26a (asserting that "Caraco's injury is traceable to Forest" because "if Forest had not listed its ... patents in the FDA's Orange Book..., then [the statute] would not independently delay Caraco's ANDA from being approved") (capitalization omitted).

But Caraco's lawsuit does not complain about Forest's decision to list the '941 patent in the Orange Book at all — much less seek a declaratory judgment that Forest's decision to list the '941 patent in the Orange Book was unlawful. Instead, as the appellate court recognized, Caraco's suit against

Forest merely seeks a declaratory judgment that its proposed generic EO products would not infringe the '941 patent if those products were manufactured or marketed. *Id.* 17a ("Caraco filed a separate action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the Hatch-Waxman [Act], 21 U.S.C. § 355(j)(5)(C), seeking a declaratory judgment that the drug described in its ANDA does not infringe Forest's '941 patent."); *id.* 28a n.10 ("Caraco has not sought a judgment of invalidity in this case.").

However, the question of whether Caraco's EO product infringes the '941 patent — the only issue as to which Caraco seeks a federal court determination — is purely hypothetical in this case because Forest has validly and enforceably promised never to assert the '941 patent against that product. And the conduct to which Caraco traces its asserted Article III injury-in-fact, is not, and cannot be, the subject of a legal claim in any event. Under the Hatch-Waxman Act, brand manufacturers *must* submit for Orange-Book listing "any patent which claims the drug for which the [brand manufacturer sought FDA approval] and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed ... engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). Thus, even if one unlicensed company's generic product would not infringe a listed patent (as Caraco's product allegedly would not in this case), the brand-name drug's manufacturer properly may list that patent in the Orange Book so long as the patent covers (or "claims") the brand-name drug and its owner reasonably could assert infringement claims against some other unlicensed generic

applicant. Indeed, the law *requires* the brand manufacturer to do so.

The distinction between claims of non-infringement, on one hand, and claims that a brand manufacturer improperly listed a given patent in the Orange Book, on the other, is particularly sharp in this case. The '941 patent claims a narrowly defined particle size of EO, which is the active ingredient in Forest's brand-name product (Lexapro®). Wholly apart from the question presented by Caraco's declaratory judgment action — *i.e.*, whether Caraco's proposed generic product does or does not contain EO particles of the size covered by the '941 patent — no one has ever suggested that Lexapro® does *not* contain EO particles of the size claimed by the '941 patent or that Forest could not reasonably assert that patent against an unlicensed applicant whose proposed generic product *does* contain EO particles of the size claimed in the '941 patent.

Regardless of whether Caraco's injury somehow can be traced the Forest's patent-listing decision — and as set forth above, that is far from clear — Forest's legitimate decision to list the '941 patent in the Orange Book is not itself "the challenged action," *Friends of the Earth*, 528 U.S. at 180, or "complained-of conduct" in Caraco's suit, *Steel Co.*, 523 U.S. at 103, and thus cannot give Caraco Article III standing to pursue this case.

To be sure, nothing would preclude the federal courts from exercising jurisdiction over this action if Caraco actually were challenging Forest's patent-listing decision. Indeed, numerous courts have recognized that unlawful patent listings can give rise to liability under the Sherman Act, and thus have

authorized generic applicants to bring lawsuits asserting such claims in federal court. *See, e.g.*, *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004) (recognizing an antitrust cause of action for sham Orange Book listings); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 n.8 (4th Cir. 2002) (same); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (same). Nor would anything preclude Caraco from bringing a "civil action for patent certainty" under 21 U.S.C. § 355(j)(5)(B)(iv) if it genuinely faced patent *un*certainty. But this is not such a case; Caraco seeks only a declaration of *non-infringement*, and that claim does not remotely depend on whether Forest's Orange Book listing was proper in the first instance.

The Federal Circuit thus erred in holding that the federal courts have jurisdiction over declaratory judgment actions like Caraco's, and this Court should grant the writ.

CONCLUSION

For the foregoing reasons, the petition should be granted and the Federal Circuit's judgment reversed.

HENRY DINGER, P.C.
Counsel of Record
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
(617) 570-1276